Development of guidelines for general practice care

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SUMMARY. The setting of standards for general practice care is receiving increasing attention in many countries. However, various problems have been noted in the procedures used for the development of guidelines. In this paper, a model for developing guidelines that fit into the specific general practice situation is presented. This model attempts to integrate current experiences in this area. Ideally, the development of guidelines should take place on various levels (central, local, practice and individual), each level involving different aims and methods. Thorough procedures must be used, in which attention is paid to the scientific validity of the guidelines, the reliability of the results, the clinical applicability, and in particular, the acceptance and adoption of the guidelines in practice.

Keywords: protocols; quality in general practice; research methodology.

Introduction

QUALITY of care and quality assurance are important items on the agenda of most policy makers, fund providers and practitioners in health care. Developing standards and guidelines is seen as one of the crucial tools in achieving high quality care. Recently, the development of practice guidelines has become so popular in medicine that some people speak of 'standardmania'.[1] In the 1980s considerable experience was gained in developing these guidelines in particular in hospital settings[2,3]. Evaluation of these activities has not been totally positive, however, and there have been criticisms.[4] It has still not been established, for instance, which method is most appropriate for developing valid and reliable guidelines.[2,5,6] A thorough analysis of the relevant scientific literature is often not carried out, doubt exists as to the procedures used for consensus and for deciding on the acceptance of specific guidelines, and the goals and status of the guidelines are often not clear. Some guidelines are based on 'hard evidence,' others on expert knowledge or the preferences of participants in the developmental procedure;[7] this is generally not made explicit in the guidelines. Perhaps the most important problem is that the results of disseminating and implementing the guidelines are disappointing.[3] Various studies have made it clear that new and valuable scientific results and practice guidelines only reach part of the target group.[8,9] Even if doctors are informed about what to do, they often do not perform according to their knowledge and skills.[10] However, most consensus procedures do not treat the implementation of the guidelines as an integral part of the procedure.[2]

A systematic evaluation of the suitability, acceptance, impact and effect of guidelines in actual practice is still lacking. The use of guidelines in randomized clinical trials may not be relevant to their use in the average practice, depending on the nature of the setting, the characteristics of the patient population, the availability of resources and the workload.[11]

Despite these problems, the development of guidelines for general practice care may be very important or even unavoidable.[12,13] Guidelines must be developed to match the needs of general practice in a way which avoids the problems mentioned above. In this paper, a model for developing such guidelines is presented, which aims to integrate current experience in this area. First, the advantages and disadvantages of central and decentralized approaches are described and a synthesis of the two approaches is proposed. Secondly, a step-by-step procedure for developing guidelines is presented with criteria for adequate procedures and for good guidelines.

Centralized versus decentralized approach

The approaches to developing practice guidelines can be considered to be of two types, both of which have their advocates. In the local or decentralized approach a local group, a group practice, or a health centre formulates guidelines on the basis of available expertise and experience, and attempts consensus through discussions. If necessary, literature is studied or experts are consulted and other parties may also be involved. This approach is aimed mainly at arrangements for the regional, local or practice situation. The advantages of this approach are that it is an educational process for the participants, it increases their sense of commitment to and 'ownership' of the guidelines, and the chance of acceptance is good. A disadvantage of the approach is that the task is probably too difficult for the average general practitioner, who may well lack the necessary skills and expertise.[14] Furthermore, this approach may lead to unacceptable guidelines that reinforce existing obsolete procedures.

In the centralized approach a group of expert general practitioners develops guidelines with a broad, preferably national, legitimacy on the basis of an analysis of scientific literature and clinical experience. The advantages of this approach are its scientific basis and its contribution to more uniformity in general practice care. For individual general practitioners this approach may be beneficial, as it is becoming increasingly problematic for them to keep up with new scientific developments in all relevant areas. A potential problem however, is that care providers may reject guidelines that they have not developed themselves. To a certain extent, people will always want to re-invent new 'products' and adapt them to their own specific situation.[15]

The advantages and disadvantages of the two approaches are summarized in Table 1.

Examples of the two approaches

Different models are used for the development of guidelines using the centralized and decentralized approaches.

Consensus development of the National Institutes of Health. Since 1977, more than 100 national consensus guidelines have been developed using a specific procedure in the United States of America, mainly for hospital care.[2,6] The main aim has been the transfer of research results to practice, and topics that concern new developments and technologies in health care have been selected. During a consensus meeting lasting between two and

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Submitted: 31 October 1991; accepted: 2 July 1992.

two and a half days, an independent panel, composed of experts from the fields of medicine, epidemiology, and health economics, as well as representatives of the community, attempts to evaluate whether the innovations under discussion are safe, cost effective and justified. The panel listens to presentations from experts in the field. Subsequently, a discussion with a large audience takes place. At the end of the second day the panel formulates a final statement which is then presented on the last half day and offered to the press. In other counties, such as Canada, the United Kingdom, the Scandinavian countries, and the Netherlands, this procedure has been adapted to place more emphasis on analysing the scientific literature and preparing the consensus meeting thoroughly.[6]

National standard setting by the Dutch college of general practitioners. Since 1989 the Dutch college has presented national standards and guidelines for general practice care.[9] An independent advisory board selects subjects suitable for standard setting. In between nine and 15 monthly sessions a working party of general practitioners, varying from volunteers who are very well informed to those with a slightly more than average interest in the subject, draws up a draft for the standard. This process is supported by members of the college staff, who also edit the standard. The draft is sent for comment to 50 general practitioners selected at random from members of the Dutch college. Additional comments are obtained from relevant specialists. The revised draft is then assessed by an independent authorization committee, consisting mainly of professors in general practice. This committee scrutinizes the scientific justification of the proposed guidelines. After approval, the standard is published in the college journal *Huisarts en Wetenschap*, with a summary of the guidelines on a plastic card for quick reference. More than 30 sets of practice guidelines have been developed to date; the aim is to publish eight to 10 further sets annually together with a few updated standards. Considerable attention is paid to the implementation of the guidelines: for most of the standards specific programmes for continuing medical education are developed. Evaluation of the awareness and acceptance of the national standards among Dutch general practitioners has revealed a positive attitude towards the standard setting initiatives taken by the college.[9]

The North of England study of standards and performance in general practice. In the north of England local small groups of general practitioner trainers, sometimes supported by a medical specialist, have developed standards, by means of a structured procedure, for a series of general practice topics.[14,16] The procedure included reading literature, examining existing standards, developing branching logic skills, and group discussions. Each group developed its own standards and the results were shared with the other groups. In this way, expertise was exchanged among a large group of general practitioners in the region. This project was unusual in that the impact of setting standards on practice was evaluated for some of the standards, for example, health problems in children. Improvements were found in the prescription and follow-up behaviour of general practitioners, and in the patients' compliance with medication and in their health. Evaluation of the developmental process revealed that standard setting is intrinsically difficult and calls for interpersonal, technical and clinical skills; this combination of skills is not widely available.

Development of guidelines on various levels

As some doctors favour the local approach to the development of guidelines and others the centralized approach, the setting of standards, guidelines and goals for patient care in general practice on various levels, each level involving different participants and aims is proposed.[17] Specific aims and methods are important at each level (Table 2). At a national level, a scientific basis and broad legitimacy are important. At a local level, the development of local arrangements, based on national guidelines, among general practitioners themselves, and between general practitioners, hospitals and other care providers is crucial. At a practice and individual level specific objectives should be set by general practitioners and other practice workers, on the basis of available guidelines.

Thus, the processes of guideline development at the different levels should be complementary. In this way, the expertise of the different levels is used optimally, and a sense of commitment is promoted.

Methods for developing practice guidelines

In order to develop adequate and effective guidelines for practice the following requirements must be met.

- A thorough procedure is needed for analysing the scientific literature, reaching consensus and formulating guidelines, in order to enhance the credibility and reproducibility of the results.[2,5,6,18,19]

Table 1. Advantages and disadvantages of the centralized and decentralized approaches.

Type of approach	Advantages	Disadvantages
Decentralized[a]	Educational	Time-consuming, difficult job
	Commitment of target group, 'ownership'	Lack of specific expertise/skills
	Guidelines adapted to local situation	No systematic analysis of literature
	Acceptance/adoption may be easy	Problems of group processes[b]
		Average performance as guideline
		Different guidelines in same district
Centralized[c]	Sound scientific basis	Time-consuming, expensive
	Structured, thorough procedure	Target group not involved, 'no ownership'
	Broad professional basis	Necessarily global
	Uniformity	Not adapted to specific needs and local situations
	New insights/research	Provokes fear and misunderstanding among GPs
	Gives direction to CME/vocational training schemes	Potential abuse by 'outsiders'[d]
	Improves understanding of general practice in the community	
	Efficient approach	

CME = continuing medical education. [a]Small group approach. [b]Dominant participants in group, no group leaders, unstructured procedures and so on. [c]Consensus procedure on national/regional scale. [d]Government, fund providers, patients.

- The guidelines must be founded on an adequate mixture of scientific basis, clinical applicability and feasibility in day-to-day care. For many aspects of general practice, scientific data are not available, are controversial, or are not immediately applicable in practice.[2,7]
- The aims of the guidelines should be clearly and explicitly defined.[20] For example, are they an aid for practice, a tool for assessment, a summary of available knowledge, a way to demarcate the task of the general practitioner, a support for education, a set of criteria to evaluate the quality of care by general practitioners, or a tool for external control?
- Guidelines are not self-implementing: procedures for implementation and evaluation should be built into the development of guidelines from the start.[2]

A general model for the development of guidelines is presented here, focusing particularly on centralized guideline setting, with sufficient expertise and resources available. Parts of the model could also be used in local standard setting. As this model merely attempts to indicate possibilities, it should not be followed rigidly, but ideas from the model could be used to develop a specific method adapted to the demands and characteristics of a particular national, regional or local situation and to the available resources (time, money, support, skills and so on).

Preparation

The emphasis of this phase is on creating the conditions required for developing the model and achieving optimal results from the consensus procedure.

Selection of a topic. First a relevant topic is selected. Various criteria may be considered in selecting a topic: it deals with an aspect of the general practitioner's work that is perceived by general practitioners, patients, or others, as a problem of quality; it relates to unexplained variation in practice; it implies beneficial consequences for the health status, well being, or satisfaction of patients (there may also be important cost implications); it involves new research findings, possibly rendering old procedures obsolete, or a controversy or uncertainty exists regarding a certain aspect of the general practitioner's work; it represents a common, frequently occurring problem in general practice. In all cases the development of guidelines for the topic should appear possible, there should be a good chance that consensus will be achieved and evaluation of actual care should be feasible. Ideally, scientific findings should be available for the development of the guidelines.

Analysis of the problem. A preliminary analysis is carried out in which the following questions are answered: What is known about actual care in general practice? What are the possible gaps in performance (analysis of data on morbidity, on performance, and on interdoctor variation)? For which aspects of performance are the guidelines required? Are there specific decisions taken in the general practitioner's work that would be supported by the guidelines? What barriers might be expected as far as adherence to the guidelines is concerned? How may these implementation problems be taken into account in the consensus process? This analysis can be carried out by studying literature and existing research data from general practice, or by surveys of or interviews with doctors, patients or policy makers.

Selection of experts. A group of general practitioners who are competent, having specific scientific expertise on the topic, and recognized as having general practice experience, is selected. This group should be small, comprising between five and 10 people, and ideally should be supported by a staff member of the organization which has taken the initiative to develop the guidelines. The choice of the experts often determines the choice of guidelines and it is therefore important to select a balanced group in which all the existing expertise is available. The credibility of this group depends on their competence: the status of the people in the group, based on their competence in general practice and science; their recognition: the extent to which general practitioners can identify with the group of developers; and their representativeness: the extent to which the group represents the opinions of the majority of general practitioners.

Assignment for the working party. Finally a detailed plan of the consensus procedure and the further steps that need to be taken is drawn up. The topic and the aim of the guidelines must be well defined, and a time schedule must be presented.

Developing draft guidelines

In the next phase the working party develops a set of draft guidelines, placing emphasis on their scientific validity and clinical relevance.

Table 2. Development of practice guidelines at different levels.

Level	Aim	Body/individual involved	Nature of involvement
National, regional	Scientific basis Broad acceptance by profession Improve understanding of general practice Give direction to CME and QA	Professional organizations Experts in general practice Representatives of other parties[a]	Structured procedures Delphi procedures Consensus conferences
Local	Development of local guidelines and arrangements between GPs and other care providers	Groups of collaborating GPs Specialists, hospitals Other disciplines	Peer review Group consensus methods
Practice	Development of practice goals and objectives	GPs Other workers in the practice Patient representatives	Quality circles[b] Structured discussions in practice meetings
Individual	Setting of individual objectives for quality improvement	GPs Peers	Self audit Peer review

CME = continuing medical education. QA = quality assurance. [a]Patients, insurance companies. [b]Industrial model for solving problems in which all parties, including patients, may be involved.

Analysis of literature. A systematic analysis of scientific literature is undertaken. This provides a starting point for consensus discussions in the group, and demonstrates the quality of the scientific evidence available. It is still unclear which method of analysing literature is most effective and whether a meta-analysis, in which the results from several studies are summarized in a quantitative way, is the best method for the development of guidelines in general practice. For many procedures and interventions in general practice, scientific evidence is lacking and it can be difficult to translate the findings of a meta-analysis into day-to-day practice care. For this reason, local guidelines and relevant protocols are also collected and studied, and the opinions of specialists are sought.

Consensus on draft guidelines. By means of discussions, the group of experts critically considers the results of the literature analysis and the collection of other data. In this way it becomes clear as to where hard evidence is lacking and where additional clinical expertise is needed in the development process. The discussions should result in draft guidelines and in a scientific justification of these guidelines. The following should be avoided: the selective use of scientific findings; reaching a forced consensus owing to pressure of time; domination of the consensus discussion by certain members of the working party, in particular those who write best or are verbally most convincing; domination by feasibility discussions thus suppressing new ideas. Formalizing the consensus discussions and the development work might lead to more reliable results.

Experience with consensus development has revealed several important criteria which need to be fulfilled in order to achieve good practice guidelines.[2,3,7,12,14,17,19]

- Validity. The guidelines should lead to the expected health or cost outcomes. This is determined by several factors, for example whether a thorough literature review has been carried out, whether the relation between scientific evidence and guidelines has been demonstrated clearly, and whether adequate use of clinical expertise has been made. For each of the guidelines it should be clear whether it is based on hard evidence, clinical expertise or the preferences of practitioners or patients.[3]
- Reliability. It should be considered whether another group of experts would have produced the same guidelines. The guidelines should be interpreted and applied in a consistent manner by different general practitioners in similar clinical situations.
- Clinical relevance and applicability. The guidelines should be written from the perspective of problem solving situations in general practice; integrating the guidelines in day-to-day care must be simple; the guidelines should identify clearly all the patient populations to which they apply and the conditions under which they are (in)appropriate.
- Comprehensiveness and specificity. The guidelines should be comprehensive, specific and detailed. They should include all the major relevant additional factors that must be taken into consideration, such as severity of disease and comorbidity, and they should describe exactly for which cases the procedure is recommended.
- Flexibility. Specifically known or generally expected exceptions to the guidelines should be clearly stated. The guidelines should allow for clinical judgement or patient preferences and for clinically relevant conditions in practice.

Consensus

The next phase involves presenting the guidelines to a broader audience. The emphasis during this phase lies in obtaining a broad basis of support for the guidelines, information on their feasibility and applicability in practice, and a formal, independent authorization.

Testing the guidelines. Insufficient attention is often given to the testing of guidelines in actual practice and it can therefore remain unclear whether the guidelines are broadly applicable in different practice settings. Ideally, the guidelines should be tested by means of a pilot study in different practices or by developing a set of prototypical cases and asking a sample of general practitioners to react to these.

Consensus procedure. It is important to acquire a broad basis for the guidelines. This can be achieved by involving the target group of general practitioners and other interested parties in the consensus development process at the earliest stage possible, and by inviting their opinions. General practitioners may then identify with the guidelines more easily as a sense of 'ownership' is achieved. Moreover, barriers to the implementation of the guidelines may be detected. It may also become clear as to what extent the guidelines meet the needs of general practitioners and others, which can help in translating 'scientific' guidelines into 'practice' guidelines.

The opinions of interested parties and target groups may be obtained in different ways.

- Consensus conference. During a conference with a large group of representatives from the target group and from other interested parties, the guidelines are presented and justified. The audience is given the opportunity to criticize and add to the guidelines in a structured manner. Recently, experience has been obtained in the Netherlands with anonymous voting procedures and voting machines to make the results more objective.[21]
- Survey. A sample of the target group or external consultants are asked to comment on the guidelines using a well organized questionnaire or in interviews.
- Group interview. The guidelines are discussed in a systematic way at small group meetings of general practitioners or others.[19]
- Delphi procedure. A panel of representatives from the target group is selected and anonymously gives its opinion through questionnaires. Feedback on the results is presented to the panel after each round of questioning. In some rounds consensus can be achieved on specific guidelines.[22]

Each of these methods has its advantages and disadvantages. The crucial element in all the methods is the selection of participants, as they should represent the opinions of the involved parties as closely as possible. It is also important that the procedures used are well structured and formalized, making the results more defensible and reproducible. Criteria for consensus — for taking decisions and for handling disagreement — should be formulated beforehand and strict regulations for consensus discussions should be adopted.

Authorization. Data from the testing of the guidelines and from the consensus activities should be studied and incorporated in a new draft of the guidelines. Formal authorization is then sought for this 'product'. This may be achieved through an independent expert panel in which different parties are involved (consensus method used in the USA);[2,6] through an independent scientific board that controls the process and outcomes of the consensus development (consensus method of the Dutch college)[9] or through formal acceptance by representatives of government,

fund providers and/or patient organizations. This official seal of approval may play an important role in the final acceptance of the guidelines by the target group.

Formatting the guidelines

The emphasis in this phase lies on the development of a final 'product' and the presentation of the guidelines in a clear, didactic and attractive style. Formatting refers to the physical layout of the guidelines and the adaptation of this format to the specific situation in which it is to be used. Different formats may be appropriate for different users, goals, settings and means of dissemination. Various criteria for good formatting have been formulated in the literature.[2,17,23–25]

Clarity. The guidelines must be presented in a logical, well-organized manner and the language used must be appropriate. Branching logic, flow charts and a stepwise approach should be used but ambiguous language (such as 'mostly', 'sometimes' or 'may be adequate') and abstract terms must be avoided. The guidelines should include an index to the major elements and a glossary of terms.

Didactic style. Acquiring insight into the guidelines and the recommendations made should be easy. The form and language of the guidelines must be adapted or linked to daily medical practice, that is, to the structure of the consultation or the problem-solving process in general practice. Specific recommendations for behaviour in specific situations must be presented. The guidelines should concentrate on essentials, that is, the key points in diagnosis and management, leaving out less important details. The transition from guidelines to educational tools must be easy and it should be possible to translate the guidelines easily into evaluation indicators and criteria and also into audit and assessment instruments.

Attractive style. This concerns the physical layout and the communicative value of the guidelines. The presentation of the guidelines should provoke interest and a positive attitude and this can be achieved by using a spacious layout, no technical jargon or scientific references, attractive typefaces, graphic aids, bold typeface where appropriate, subheadings and highlighting techniques and short summaries of the key recommendations.

Implementation

In this phase the practice guidelines are presented to the target population. The general practitioners are encouraged to take notice of them and to use them in practice, in vocational training, in continuing medical education, in medical audit and in developing arrangements with their partners in the practice or in the locum group.

Dissemination. This involves the diffusion of the guidelines among the target group. An effective strategy is required to inform general practitioners about the guidelines, particularly if they were developed at a central level. Various studies have demonstrated that guidelines published in scientific journals do not reach care providers.[26–28] A variety of approaches is necessary and the dissemination should be maintained for a prolonged period of time in order to be successful.[29] The use of the mass media — scientific journals, professional journals for general practitioners, newsletters, audio-visual communications and popular versions in magazines and newspapers for patients — should be combined with personal approaches — courses, meetings to discuss guidelines with colleagues, diffusion through local networks, use of individuals who are opinion leaders and visits of trained consultants to general practitioners.[23,24,30]

Developing implementation programmes. Specific implementation programmes, developed to encourage the acceptance and adoption of guidelines by the target group, are required.[25] Having heard about the guidelines, general practitioners must be encouraged to give them a place in their normal routine. This phase is perhaps the most difficult. The practice setting, as well as personal and patient factors, play a role in achieving changes in medical practice.[31] Different general practitioner groups may require different methods to motivate them to make practice changes. Specific programmes and interventions should be designed to promote the desired changes.

Evaluation

The guidelines must be updated regularly on the basis of new research results and of experience with the application of the guidelines in practice.

Research on impact and effect. In order to evaluate how the guidelines are received and applied in practice three important questions must be answered.[2] Are the guidelines received, read, understood, accepted and remembered by the general practitioners and other practice workers involved? What is the impact of the guidelines on clinical practice and to what extent are they used in day-to-day care? Are the guidelines effective, that is, do they succeed in achieving their aims in terms of health outcome, patient satisfaction and health care costs?

Updating. A procedure must be developed for updating the guidelines every three years or whenever new scientific information becomes available. A review of the guidelines should be scheduled as part of the evaluation process.

Parts of this model may be useful for the development of guidelines on a local and practice scale, in particular selecting a topic and analysing the problem; analysis of the literature and available guidelines; consensus discussions among all interested parties; testing the guidelines in real practice; presenting them in a clear, well-organized style; follow up of the adherence to the guidelines and updating them regularly. A thorough approach should also be employed in decentralized guideline development.

Conclusion

Guidelines for the quality of care in general practice may be an essential component of quality assurance. They render general practitioners' performance transparent to the 'outside world' and provide support for general practitioners themselves. They may help solve the tension between the demands of the community to obtain a detailed impression of general practitioners' work, and the tendency of doctors to improve the quality of their work only within their own group of peers. To develop good practice guidelines a thorough procedure is essential. Current experience with standard setting and guideline development in general practice suggests that the following considerations may be valuable:

- Achieving scientific validity through a systematic analysis of the literature and through serious evaluation of the new guidelines.
- Acquiring reliable results through formal procedures for achieving consensus, and by discussing opinions and clinical experiences.
- Obtaining a broad basis for the guidelines among involved parties, thereby creating a sense of 'ownership' through a

process of development on several levels (central, local, practice and individual) with different aims.
- Testing the applicability of the guidelines in practice, using the comments of general practitioners, other care providers, patients and policy makers.
- Considering the implementation of the guidelines from the start of the process.

A critical attitude towards consensus development is nevertheless warranted. Skrabanek illustrated certain dangers of consensus methods by examining the consensus guidelines for lowering cholesterol levels by dietary treatment.[4] He compared the consensus conference in question to a synod of bishops, the purpose of which is to 'solve' uncertainties by compromise. Another danger is that the conviction and positiveness of the gurus of medicine of the past will be replaced by the, albeit more democratic, certitude of the expert group, which translates existing values and opinions into consensus guidelines. The differences in accepted medical procedures in different countries provides a warning in this respect.[32] The development of practice guidelines may be an important step in assuring quality in general practice care. However, it is important to keep an open mind at all times in dealing with conflicting and possibly unfavourable information. Guidelines are never more than a summary of the best information available at a specific moment,[33] and this information may rapidly become obsolete.

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